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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,112

07/11/2006

Michael Wilson

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,112	Applicant(s) WILSON ET AL.	
	Examiner SHERIDAN R. MACAULEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,13-27,32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-12 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/2006, 4/10/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-27 and 31-33 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-12 and 31) and a staphylococcal bacteriophage as the species of bacteriophages and SnC36 as the species of photosensitizers in the reply filed on November 10, 2008 is acknowledged. The traversal is on the ground(s) that examination of all claims would not place a serious search burden on the examiner. This is not found persuasive because an examination of all claims would be a serious search and examination burden if restriction were not required because the inventions require a different field of search (for example, employing different search queries, such as searching for method steps in the method recited in the claims of the nonelected invention) and the prior art applicable to one invention would not likely be applicable to another invention.
2. The requirement is still deemed proper and is therefore made FINAL.
3. It is noted that applicant has stated that claims 2 and 6-7 read on the elected species of bacteriophages (applicant elected "staphylococcal bacteriophage"). However, as stated in the office action mailed on August 8, 2008, election was required of one species of bacteriophage recited in claims 2, 6 and 7, such as a staphylococcal bacteriophage (recited in claim 2), phage 53 (recited in claim 6) or phage 75 (recited in claim 7). Since only claim 2 reads on the elected species "staphylococcal bacteriophage," claims 6 and 7 have been withdrawn.

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4. Claims 6-7, 13-27 and 32-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups and species, there being no allowable generic or linking claim.
5. Claims 1-5, 8-12 and 31 are examined on the merits in this office action.

Claim Objections

6. Claim 11 is objected to because of the following informalities. It is recommended that the claim be amended as follows: The term "n a pharmaceutically acceptable carrier" should be amended to term "in a pharmaceutically acceptable carrier", or some other appropriate term. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 4, 8, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogset et al. (WO 02/44395; document cited in IDS). The claims recite a composition comprising a conjugate of a photosensitizer, and a bacteriophage. The claims further recite that the photosensitizer is covalently linked to the bacteriophage, that the photosensitizer is present at 0.01 to 200 micrograms per ml, and that the solution

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comprises a pharmaceutically acceptable carrier or an additional component, such as a buffer or preservative.

9. Hogset teaches a photosensitizing agent attached to a bacteriophage (p. 20, line 21-p.21, line 1). The reference teaches that the two may be attached by a linkage, such as a covalent bond (p. 20, line 21). The reference teaches that the composition may be a solution in a pharmaceutically acceptable carrier and may comprise additional components such as preservatives (p. 38, lines 3-20). Hogset teaches that the photosensitizer may be a chlorin (p. 11, lines 35-37) and may be present at concentrations in the claimed range, e.g., 0.05 micrograms per ml (p. 38, lines 33-35).
10. Therefore, the reference anticipates all of the limitations of the cited claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-5, 8-12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogset et al. (WO 02/44395; document cited in IDS in view of Embleton et al. (Journal of Antimicrobial Chemotherapy, 50:857-864; document cited in IDS). The claims recite a composition comprising a conjugate of a photosensitizer, such as a tin (IV) chlorin e6 (SnCe6), and a bacteriophage, such as a staphylococcal bacteriophage. The claims further recite that the photosensitizer is covalently linked to the bacteriophage, that the photosensitizer is present at 0.01 to 200 micrograms per ml, that the bacteriophage is present at 10^5 to 10^{10} pfu per ml, that the composition comprises a source of calcium ions, such as calcium chloride, and that the solution comprises a pharmaceutically acceptable carrier or an additional component, such as a buffer or preservative.

15. Hogset teaches composition comprising a photosensitizing agent attached to a bacteriophage (p. 20, line 21-p.21, line 1). The reference teaches that the two may be attached by a linkage, such as a covalent bond (p. 20, line 21). The reference teaches

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that the composition may be a solution in a pharmaceutically acceptable carrier and may comprise additional components such as preservatives (p. 38, lines 3-20). Hogset teaches that the photosensitizer may be present at concentrations in the claimed range, e.g., 0.05 micrograms per ml (p. 38, lines 33-35). Hogset teaches that the virus may be suspended in PBS comprising calcium chloride (p. 47, line 31-p. 48, line 12). The reference teaches the administration of 10^3 to 10^{13} pfu per injection (p. 16, lines 1-4).

16. Hogset does not specifically teach that the bacteriophage is a staphylococcal bacteriophage and does not teach that the photosensitizer is SnCe6.

17. Embleton teaches compositions comprising conjugates of photosensitizers, such as SnCe6, and IgG (abstract). The reference teaches that the conjugate is constructed to selectively target *Staphylococcus aureus* (abstract). The reference also teaches that the photosensitizer is covalently linked to the IgG (p. 859, par. 3), that the composition may be delivered at 25 micrograms per ml (p. 859, Results, par. 1).

18. At the time of the invention, a composition comprising conjugate of a virus, such as a bacteriophage, and a photosensitizer was known, as taught by Hogset. It was further known that conjugates of photosensitizers, such as the chlorin SnCe6, and targeting molecules, such as IgG, could be used to target *Staphylococcus*, as taught by Embleton. One of ordinary skill in the art would have been motivated to combine these teachings because Hogset teaches that chlorin photosensitizers can be coupled with bacteriophage to selectively target specific cell types (p. 20, line 21-p.21, line 1). One would therefore have recognized that a bacteriophage could be used to target *Staphylococcus* in place of the IgG in the method taught by Embleton. One would

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further have been motivated to prepare a composition with the claimed concentration of bacteriophage because Embleton teaches the delivery of a wide range of pfu per injection site; one of ordinary skill in the art would have recognized that the formulation could have been prepared with the claimed range of pfu per ml in the course of routine experimentation. Furthermore, Hogset teaches that the virus may be suspended in PBS containing calcium chloride. One would have recognized that, since the preparations of Embleton are also prepared in PBS (p. 859, par. 3), a PBS such as the one used in Hogset could have been used in the composition of the combined teachings. One of ordinary skill in the art would have a reasonable expectation of success in combining the claimed teachings because Hogset teaches that many types of photosensitizers and viruses may be conjugated and Embleton teaches techniques for preparing SnCe6 conjugates. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

19. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/
Primary Examiner, Art Unit 1651